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			1623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)				
	10/585,417	MIYAMOTO ET AL.				
Office Action Summary	Examiner	Art Unit				
	SCARLETT GOON	1623				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
	/ IO OFT TO EVEIDE A MONTH!	O) OD THIDTY (OO) DAYO				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>16 O</u>	ctober 2009.					
	action is non-final.					
3) Since this application is in condition for allowar						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>34-57</u> is/are pending in the application.						
4a) Of the above claim(s) <u>34 and 35</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>36-57</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct		• •				
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. ☐ Certified copies of the priority documents have been received in Application No3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
	,					
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P					
Paper No(s)/Mail Date <u>7 July 2006 and 30 April 2009</u> .	6) Other:	,				

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 16 October 2009 in which claims 1-33 were cancelled, claims 34 and 35 are amended to change the scope and breadth of the claims, and new claims 36-57 are added.

Claims 34-57 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/JP05/00125 filed on 7 January 2005 and claims priority to Japan foreign application 2004-002478 filed on 7 January 2004. A certified copy of the foreign priority document in Japanese has been received. No English translation has been received.

Election/Restrictions

Claims 34 and 35 were previously withdrawn from further consideration in the Office Action dated 17 April 2009 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or nonelected species, there being no allowable generic or linking claim.

Newly added claims 36-57 are drawn to the elected invention of Group I, drawn to a hyaluronic acid compound in which an anti-inflammatory drug is bound to hyaluronic acid through a covalent bond via a spacer having a biodegradable region. In the reply to a requirement for an election of species, filed on 29 December 2008, Applicants elected (i) a non-steroidal anti-inflammatory drug, (ii) diclofenac, and (iii) the

compound of Formula (1) wherein Y-CO- is hyaluronic acid, R¹ is a linear hydrocarbon group having two carbon atoms which may have a substituent, R² is a non-steroidal anti-inflammatory drug residue represented by Formula (2), and n is an integer of from 1 to 3. The elected species of Formula (2) is diclofenac, wherein R³, R⁴ and R⁵ each represent a hydrogen atom and X represents a chlorine atom. This acknowledgement corrects the election stated in the Office Action dated 17 April 2009.

Claims 36-57 are examined on its merits herein.

Information Disclosure Statement

The information disclosure statements (IDS) dated 7 July 2006 and 30 April 2009 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609, except where noted. Accordingly, they have been placed in the application file and the information therein has been considered as to the merits.

Foreign patent document JP62-64802 was not considered because an English translation or equivalent was not provided to the Office, and it is not apparent that the reference was previously cited on an International Search Report.

Rejections Withdrawn

In view of the cancellation of claims 1-33, all rejections made with respect to claims 1-33 in the previous Office Action are withdrawn.

These rejections have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "R² represents a non-steroidal anti-inflammatory drug residue represented by Z-CO- or hydrogen atom, with the proviso that all R² s are not hydrogen atoms" renders the claims herein indefinite. The preamble of the claim would suggest that a non-steroidal anti-inflammatory drug must be bound to hyaluronic acid via a linker. However, the recitation "with the proviso that all R² s are not hydrogen atoms" suggests that one of the R² s may be a hydrogen. In the situation wherein there is only one R², and the recitation states "R² represents a non-steroidal anti-inflammatory drug residue represented by Z-CO- or hydrogen atom," the R² could be a hydrogen, and thus, there would be no non-steroidal anti-inflammatory drug residue conjugated to the linker. It is the Office's position that Applicants intend for at least one R² to be a non-steroidal anti-inflammatory drug residue, and thus, in order to further expedite prosecution, will interpret the claims to that effect. However, it is respectfully suggested

that Applicants amend their claim to more clearly define the intended claimed subject matter.

Furthermore, the recitation "Z-CO-" renders the claims herein indefinite because "Z" is not clearly defined in either the Specification and/or the claims. Thus, it is unclear what "Z" represents. It is the Office's position that "Z" likely refers to a portion of a non-steroidal anti-inflammatory drug residue, absence the COOH group, and thus, in order to further expedite prosecution, the claims will be interpreted to that effect. However, it is respectfully suggested that Applicants amend their claim to more clearly define the intended claimed subject matter.

The recitation "a substituent(s)" in claim 42 renders the claim herein indefinite.

The recitation "a" refers to "one," but the recitation "substituent(s)" following "a" indicates that there may be more than one substitution. Thus, the recitation appears contradictory. Applicants are respectfully requested to clarify whether there may or may not be more than one substitutent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1082963 A1 to Tamura *et al.* (of record), in view of journal publication by Perioli *et al.* (PTO-892, Ref. U).

Tamura *et al.* disclose a conjugate of hyaluronic acid and a therapeutic agent for treatment of joint diseases. The therapeutic agent is effective for treating osteoarthritis, rheumatoid arthritis and the like (paragraph 0001). The therapeutic agent for joint diseases includes non-steroidal anti-inflammatory agents (NSAIDs), cyclooxygenase-2

inhibitors, antirheumatic agents, steroids, local anesthetics, and cartilage protective agents (paragraph 0034). Non-steroidal anti-inflammatory agents include, for example, salicylic acid based agents, fenamic acid based agents, arylacetic acid based agents, propionic abid based agents, pyrazolone based agents, and oxicam based agents (paragraph 0034). The bond between the therapeutic agent for joint diseases and hyaluronic acid is a covalent bond (paragraph 0021). Chemical conjugation of hyaluronic acid with the therapeutic agent for joint diseases can occur via reaction at the carboxyl group, the hydroxyl group, or the aldehyde group originating from the reducing end of hyaluronic acid (paragraph 0072). The linkage between hyaluronic acid and the therapeutic agent can occur via a spacer (paragraph 0023). The type of spacers is not limited unless the activities of the therapeutic agent for joint diseases and the hyaluronic acid are materially affected (paragraph 0060). Spacers exemplified by Tamura et al. include C₄H₈NH- and C₈H₁₆NH- in conjugates 1 and 3 (p. 19, Table 1), which were synthesized from 1,4-diaminobutane (paragraph 0088) and 1,8-diaminooctane (paragraph 0093), respectively. The hyaluronic acid has a weight average molecular weight of 100,000 to 10,000,000 and is composed of glucuronic acid and Nacetylglucosamine (paragraph 0050). From the standpoint of the strength in viscoelasticity, hyaluronic acid having a weight average molecular weight of 700,000 to 10,000,000 is preferred. If the hyaluronic acid-therapeutic agent conjugate is to be used as a drug, it is preferably used after being formulated into a pharmaceutical preparation together with a pharmaceutically acceptable diluting agent, stabilizer and the like (paragraph 0085). The mode of administration of the drug or pharmaceutical

composition is not particularly limited and may be oral or parenteral and may be systemic or local. In general, it is preferably administered parenterally and locally, for example, intraarticularly, intravenously, intramuscularly or intradermally as injection, or percutaneously as a spraying agent, a topical cream or an ointment (paragraph 0086). If a drug bound to hyaluronic acid is administered to a living body, it is expected that the drug is retained together with the hyaluronic acid at a specific site for a long period of time and the duration of the drug action at the specific site is remarkably prolonged as compared to the case of administering the drug alone (paragraph 0012). Furthermore, it is expected that by such an effect the dosage of the drug and the frequency of drug administration are remarkably reduced as compared to the conventional administering method, resulting in greatly relieved side effects.

Tamura *et al.* further teach diclofenac sodium salt, tolmetin sodium salt, sulindac, fenbufen, indomethacin, acemetacin, among others, as examples of arylacetic acid based non-steroidal anti-inflammatory agents that can be used for conjugation to hyaluronic acid (paragraph 0034). Using cartilage protective agents, in particular matrix metalloprotease inhibitors, as an example of a therapeutic agent for joint disease that can be conjugated to hyaluronic acid, Tamura *et al.* teach that the weight ratio of the matrix metalloprotease inhibitor to the entire conjugate is preferably 0.01 to 50%, more preferably 0.1 to 10%, although the weight ratio is not particularly limited (paragraph 0024).

Applicants are requested to note that although the limitations "that the pharmaceutical agent is an arthritis-treating agent, an anti-inflammatory medicament or

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an analgesic," that it "is useful for parenteral administration," "is an injection useful for topical administration" or "is an injection useful for intra-articular administration," as recited in claims 50-53, are disclosed by Tamura *et al.*, these recitations are considered to be an "intended use" of the composition. The "intended use" of a composition will not further limit the claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Although Tamura *et al.* teach that the type of spacers is not limited and further exemplify the use of various diamino alkyl compounds as spacers in the hyaluronic acid-therapeutic agent conjugate, Tamura *et al.* do not expressly teach the use of a heterobifunctional spacer, such as that instantly claimed.

Perioli *et al.* teach the conjugation of non-steroidal anti-inflammatory agents (NSAID) to the carrier, 1,4-dihydro-1-methylpyridine-3-carboxylate, for site-targeted delivery to the central nervous system (CNS). Potential NSAIDs include diclofenac, ibuprofen, ketoprofen, tiaprofenic acid, and tolmetin (p. 715, column 2, last incomplete paragraph). The NSAID was conjugated to the carrier, 1,4-dihydro-1-methylpyridine-3-carboxylate, via an amino alcohol bridge (p. 715-716, bridging paragraph). As shown in Scheme 1 (p. 717), the amino alcohol bridge included aminoethanol, amino-isopropanol, and aminopropanol. After administration of the conjugate, oxidation of the dihydropyridine moiety sequesters the conjugate in the CNS for sustained and specific delivery (p. 716, section 2.1).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tamura et al., concerning a conjugate of hyaluronic acid and a therapeutic agent, such as non-steroidal anti-inflammatory drugs, for treatment of joint diseases, with the teachings of Perioli et al., regarding conjugation of an NSAID to the carrier 1,4-dihydro-1-methylpyridine-3-carboxylate via an amino alcohol bridge for site directed delivery to the CNS. Since Tamura et al. teach the conjugation of hyaluronic acid to non-steroidal anti-inflammatory drugs, such as diclofenac, via a 1,2-diaminobutane spacer, and Perioli et al. teach that amino alcohol linkers can be used to conjugate a NSAID to a carrier for site directed delivery, one of ordinary skill in the art would have been motivated to substitute the 1,4-dihydro-1methylpyridine-3-carboxylate carrier disclosed by Perioli et al., with the hyaluronic acid carrier disclosed by Tamura et al., in order to receive the expected benefit, as disclosed by Tamura et al., that conjugation of a NSAID to hyaluronic acid would direct the NSAID drug to a specific site, e.g. the joints, where it is expected to be retained for a long period of time. Thus, one of ordinary skill in the art would have been motivated to make the substitution as it is expected that such a substitution would yield a predictable result.

It is noted that the combined teachings of the prior art do not expressly teach conjugation of hyaluronic acid with the linker to form an amide bond and conjugation of a NSAID to the linker to form an ester bond, as instantly claimed. However, as the heterobifunctional linker only has two sites of reaction, and it is being conjugated to only two compounds, hyaluronic acid and a NSAID, it would have been *prima facie* obvious for one of ordinary skill in the art to conjugate either end to hyaluronic acid or the

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NSAID, and then conjugate the remaining end of the linker to the other compound, either the NSAID or hyaluronic acid. Furthermore, Perioli et al. only discuss one type of linker, an amino alcohol linker. One of ordinary skill in the art would have been motivated to conjugate the linker to hyaluronic acid and the NSAID, in one direction or another, with the expectation that they would yield a similar result, namely, a conjugated hyaluronic acid-NSAID conjugate that could be administered to a subject for treatment of joint diseases. Moreover, as there are only two options/directions in which conjugation of hyaluronic acid to a NSAID can occur, it would have been prima facie obvious for one of ordinary skill in the art to try both, also with the expectation that they would yield a similar result, namely, a conjugated hyaluronic acid-NSAID conjugate that could be administered to a subject for treatment of joint diseases, thereby arriving at the instantly claimed invention. The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR, 550 U.S. at , 82 USPQ2d at 1397. See also MPEP § 2143.

Applicants are requested to note that the recitation "which is obtainable by a method comprising reacting hyaluronic acid with a spacer-bound non-steroidal anti-inflammatory drug, or reacting a spacer-bound hyaluronic acid with a non-steroidal anti-inflammatory drug, and adjusting the reaction solution to alkaline conditions" in claim 43

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is not a determination of patentability. The claim is treated as a product-by-process claim and thus, the recited process limitation is not considered to further limit the product "[a] hyaluronic acid compound." See MPEP § 2113. The burden is on the Applicant to provide evidence establishing unobvious differences between the claimed product and the prior art product.

The following is a quotation from MPEP § 2113:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Applicants are requested to note that the recitations "wherein a solution obtained by dissolving the hyaluronic acid derivative in an aqueous medium to a concentration of 1.0% by weight is capable of passing through a porous filter having a pore size of 0.45 µm and a diameter of 25 mm, at a ratio of 2 mL per minute or more at a temperature of 24 C under pressure of 5.0 kg/cm²" and "wherein a solution obtained by dissolving the hyaluronic acid derivative in an aqueous medium to a concentration of 1.0% by weight is capable of passing through a porous filter having a pore size of 0.22 µm and a diameter of 25 mm, at a ratio of 2 mL per minute or more at a temperature of 24 °C under pressure of 5.0 kg/cm²" in claims 44 and 45, respectively, and the recitation "which is capable of being pushed out from an injector" in claims 46 and 54, are considered to merely state the results of the limitations in the claim. Thus, it adds nothing to the patentability or substance of the claim. When, as here, the prior art appears to contain the exact same ingredients and Applicants' own disclosure supports

the suitability of the prior art composition as the inventive composition component, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See also MPEP § 2112.01. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

It is noted that the Tamura *et al.* and Perioli *et al.* references do not expressly teach sterilization of the conjugates through a filter, as indicated in claim 48. However, one of ordinary skill in the art is well aware that filtration through a filter of that pore size is one method of sterilization, which is commonly performed prior to administration of a drug to a subject to avoid and/or minimize administration of contaminants.

With respect to the art rejection above, it is further noted that the references do not teach a kit which comprises the hyaluronic acid compound solution in an injector or syringe, as indicated in instant claims 55-57. However, Tamura *et al.* expressly teach that the hyaluronic acid conjugate with a non-steroidal anti-inflammatory drug can be used for treatment of osteoarthritis and rheumatoid arthritis by administering the conjugate intraarticularly as an injection. Thus, as the mode of administration is

disclosed, and all of the reagents and supplies used for administration are readily available and known to be used in the intraarticular treatment of arthritis, it would have been *prima facie* obvious for one of ordinary skill in the art to prepare everything into a kit ready for a practitioner to administer to a patient, thereby minimizing the number of manipulative steps necessary by the practitioner which would minimize the possibility of contamination during preparation of the drug for administration. Furthermore, kits are regarded as a composition with a set of instructions. Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004).

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Insofar as Applicants' arguments, filed 16 October 2009, with respect to the rejection of claims 1-27 made under 35 USC § 103(a) as being unpatentable over EP 1082963 A1 Tamura *et al.*, in view of JP 9-188705 to Miyamoto *et al.*, are still applicable to the instant rejection, Applicants' arguments have been fully considered but they are not persuasive in view of the modified grounds of rejection presented above.

Applicants argue that the presently claimed invention recites an aminoalkyl alcohol as a spacer which is bound to the drug via an ester bond. Furthermore,

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Applicants argue that conjugation via a diaminopropane linker, as disclosed in Tamura et al. and Miyamoto et al. had no effect on the test system of the invention, and thus, the instantly claimed invention exhibits unexpected superior properties as compared to the conjugate disclosed in Tamura et al. This argument is not persuasive in view of the modified grounds of rejection presented above. Specifically, Perioli et al. disclose an aminoalkyl alcohol linker as instantly claimed. As discussed in the rejection above, one of ordinary skill in the art would have been motivated to substitute the 1,4-dihydro-1methylpyridine-3-carboxylate carrier disclosed by Perioli et al., with the hyaluronic acid carrier disclosed by Tamura et al., in order to receive the expected benefit, as disclosed by Tamura et al., that conjugation of a NSAID to hyaluronic acid would direct the NSAID drug to a specific site, e.g. the joints, where it is expected to be retained for a long period of time. Moreover, as there are only two options/directions in which conjugation of hyaluronic acid to a NSAID can occur, it would have been prima facie obvious for one of ordinary skill in the art to try both, also with the expectation that they would yield a similar result, namely, a conjugated hyaluronic acid-NSAID conjugate that could be administered to a subject for treatment of joint diseases, thereby arriving at the instantly claimed invention. The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR, 550 U.S. at ____, 82 USPQ2d at 1397. See also MPEP § 2143.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art, as discussed in the modified ground of rejection presented above.

Conclusion

No claim is allowed. This rejection is made NON-FINAL due to the new/modified grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623 SCARLETT GOON Examiner Art Unit 1623